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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,063	03/15/2004	Shu-Ping Yang	1443.153US1	1251
21186	7590	12/11/2006		EXAMINER
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				MAIER, LEIGH C
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,063	YANG ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 October 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 - 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/05, 11/14/05</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 11-21 in the reply filed on October 5, 2006 is acknowledged. The traversal is on the ground that searching every invention would not constitute a burdensome search with no further reasoning. This is not found persuasive. As demonstrated in the restriction requirement, the search of the two inventions is not considered coextensive. The requirement is still deemed proper and is therefore made FINAL. The examiner further acknowledges Applicant's election of "mannose-6-phosphate" as the species as required. However, upon a review of the art, this species requirement is withdrawn. Claims 1-10 are withdrawn as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaginal atrophy and/or "the promotion of vaginal epithelial cell proliferation/differentiation in a patient in need thereof," does not reasonably provide enablement for the full scope of known vaginal conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The state of the prior art;
- (6) The relative skill of those in the art;
- (7) The predictability or unpredictability of the art; and
- (8) The breadth of the claims.

The claims are drawn to the treatment or prevention of a "vaginal condition" without limit. However, the specification discloses the promotion of epithelial cell proliferation. It is unclear as to how this activity would necessarily be beneficial to the wide variety of known vaginal disorders—from microbial infections to vaginismus to vaginal neoplasia, to name a few. It is noted that the specification addresses the "overgrowth of pathogens," but the discussion is in the context of an infection that results from a thinning epithelium. With no known antimicrobial activity, it is unclear how this agent would be expected to produce a beneficial result when there is no underlying problem with the vaginal epithelium. With respect to a condition such as neoplasia, it would be expected that the administration of an agent that promotes epithelial proliferation would, if anything, have a harmful effect. Prevention adds another layer of difficulty, because other than women with low estrogen, the specification does not indicate exactly what patient population is to be treated and how this population is to be selected.

Therefore, although the skill in the art would be relatively high, and the art (with respect to treatment, not prevention) would be reasonably predictable, the scope of the invention includes many disorders for which the instant treatment would be expected to be ineffective or

even contraindicated. In view of the foregoing, one of ordinary skill would require undue experimentation in order to use the invention commensurate in scope of the instant claims.

Allowable Subject Matter

The art of record does not teach the intravaginal administration of a mannose phosphate for the treatment of vaginal atrophy or something to the effect of "the promotion of vaginal epithelial cell proliferation/differentiation in a patient in need thereof." Prevention would also be allowed if limited to the population of women with low estrogen. It is noted that "low" could be considered a relative term, but one of ordinary skill would be apprised of the range considered, so it is the opinion of the examiner that this term would not be indefinite. Ferguson (US 5,520,926) teaches the administration of mannose phosphates for the acceleration of wound healing. The reference does not teach or fairly suggest the treatment/prevention of vaginal atrophy or the promotion of vaginal epithelial cell proliferation/differentiation.

Art Unit: 1623

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
December 6, 2006